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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,111	11/20/2000	Christopher Marriott	REF/MARIOTT/	3979

7590 01/14/2002

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[REDACTED] EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/646,111	Applicant(s) Marriott
Examiner Susan Tran	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 21, 2001
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.
4a) Of the above, claim(s) 6, 11, and 14-17 is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-5, 7-10, 12, 13, 18, and 19 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are objected to by the Examiner.
11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)
16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) Interview Summary (PTO-413) Paper No(s). _____
19) Notice of Informal Patent Application (PTO-152)
20) Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicant's Declaration filed 20/11/00, Preliminary Amendment A filed 11/20/00, and Election of Species filed 12/21/01.

Election/Restriction

Applicant's election without traverse of species a- (lactose monohydrate crystal) in Paper No. 7 is acknowledged.

Claims 6, 11, and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 contains the trademark/trade name "carbopol 93TM". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the

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claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe carbomer and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al. US 4,725,387.

Hirao teaches a process of shaping crystals of sugar alcohols by obtaining a saccharified starch solution with high maltose content, allowing crystallization, and separation (column 2, lines 38 through column 3, lines 1-11). The viscosity of the solution can be regulated by the addition of water-soluble organic solvent, or elevated temperature (column 4, lines 45-68; and example 1). Hirao does not teach the viscosity of less than 25 Pa.s at a shear rate of 1s^{-1} .

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However, no criticality is seen in the particular viscosity since the prior art obtains the same result desired by the applicant, e.g., a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape (column 7, lines 33-53). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable viscosity of the solution to obtain the claimed invention.

3. Claims 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al., and Douglas et al. US 5,635,200.

Hirao is relied upon for the reason stated above. Hirao is silent as to the teaching of carbomer as a starch or binder in an aqueous solution. However, carbomer is a well known starch or thickener, or binder in pharmaceutical art. Douglas teaches an oral administration composition comprising starch or carbopol as an aqueous solution thickener (column 7, lines 22-32). Hence, it would have been obvious for one of ordinary skill in the art to modify Hirao's starch solution using carbopol taught by Douglas. The unexpected result is free flowing crystal having desire size and shape.

4. Claims 7, 12, 13, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirao et al.

Hirao is relied upon for the reasons stated above. Hirao does not teach the specific sugar alcohol, i.e., lactose monohydrate. However, Hirao does teach other sugar alcohols, e.g.,

sorbitol, maltitol, or maltose monohydrate (columns 2-4). Therefore, it would have been obvious for one of ordinary skill in this art to, by routine experimentation select lactose monohydrate as one of the well known sugar to obtain the claimed invention. The unexpected result is a crystalline composition that is non-hygroscopic, free flowing, and can be in any desire size and shape.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
PRIMARY PATENT EXAMINER
TECHNOLOGY CENTER 1600